DOCKET NO.: ALLE0068-100
(17326 CIP2)
Ser. No. 10/071,826

PATENT

REMARKS

Upon entry of this response, claims 1, 4, 6, 8-15, 18-20 and 32-35 will be pending. Amended claim 13 is supported by the specification at, for example, page 31, lines 13-17. New claim 34 is identical to claim 33, except that new claim 34 recites only botulinum toxin type A. New claim 35 is identical to claim 33, except that new claim 35 recites only hyperplasic and neoplastic mammary gland cells. No new matter is added.

As a preliminary matter, Applicant notes that claims 6 and 18 (both reciting botulinum toxin type A) are not being rejected on any ground. **Applicant respectfully requests that the Office clarifies that claims 6 and 18 are deemed allowable.**

I. Claims are enabled

Highlight: It was well known that botulinum toxin type B-G can substitute for type A. Thus, claims directed to the use of botulinum toxin types B-G are fully enabled.

Claims 1, 4, 7-17, 19, 20, 32 and 33 are rejected under 35 U.S.C. §112, first paragraph. The Office Action states that although the methods of using a botulinum toxin type A for treating a mammary gland disorder are enabled, the methods of using botulinum toxin types B-G are not enabled.

The methods of using botulinum toxin types B-G are enabled because botulinum toxin types B-G are from the same family and all have the same general physiological effects (see specification at page 11-14). Additionally, **it is well known that types B-G can be used clinically in ways that are similar to type A.** For example, prior to the filing date of the present application (December 7, 1999), Schantz discloses:

> Seven known serotypes of botulinum toxin (A through G) have been isolated and characterized ..., and it is likely that types other than type A will be used clinically, particularly in patients who develop immunity to type A. Furthermore, evidence is accumulating to show that different types bind to different acceptors and may have subtle differences in their mode of action and that **they could therefore complement type A in clinical applications.**

Schantz et al., Microbiological Reviews, 1992, page 80-99 (previously submitted). To emphasize, prior to the priority date of the present application, the art fully recognizes that botulinum toxin types B-G may be used to "complement" or "substitute" botulinum toxin type A for treating a condition, when a patient becomes less responsive to botulinum toxin type A due to antibody build up against the type A. **As it was well known that botulinum toxin type B-G can substitute for type A, the claims directed to the use of botulinum toxin types B-G are fully enabled.**

II. Claims 12 and 13 are not obvious over Schwartz

Highlight: "Mammary gland disorder associated with hyperplasic, hypertonic or neoplastic cells" are different from "neuromyotonia" (Schwartz).

Claims 12 and 13 are rejected under 35 U.S.C. §103(a) as being obvious over Schwartz et al. (Movement Disorders, 1998 13(1): 188-190, hereinafter "Schwartz").

As clarified by the amendment, claims 12 and 13 relate to the treatment of a mammary gland disorder associated with hyperplasic, hypertonic or neoplastic cells. One of ordinary skill knows that:

- "Hyperplasic" or 'hyperplasia" is a general term for an increase in the number of the cells of a tissue causing it to increase in size.

- "Hypertonic" cell environment has a higher concentration of solutes than in the cytoplasm.
- "Neoplastic" or "neoplasia" is abnormal, disorganized growth in a tissue/cell.

Schwartz does not teach or suggest that a botulinum toxin can be used to treat a mammary gland disorder associated with hyperplasic, hypertonic or neoplastic cells.

Schwartz simply teaches that a botulinum toxin can be used to treat breast muscle tissues that are in spasm. For example, the title of the Schwartz article is "Neuromyotonia in a Muscle Flap Producing a Convulsing Breast: Successful Treatment With Botulinum Toxin". One of ordinary skill knows that "Neuromyotonia" is spontaneous muscular activity resulting from repetitive motor unit action potentials of peripheral origin, which causes spasm. Accordingly, mammary gland disorder associated with hyperplasic, hypertonic or neoplastic cells and "neuromyotonia" are very different conditions.

The Office Action further states that, "Intrinsically, the treatment of the said disoders with the botulinum toxin would cause about 20% - 100% reduction in the diameter of the [hyperplasic, hypertonic or neoplastic, *sic*] mammary gland tissue...". This statement is not logical because the patient being treated for the neuromyotonia reported in Schwartz is not even reported to have any hyperplasic, hypertonic or neoplastic mammary gland cells to be reduced.

Since Schwartz does not teach or suggest the administration of a botulinum toxin to treat hyperplasic, hypertonic or neoplastic mammary gland cells, claims 12 and 13 are patentable over Schwartz.

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In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,

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